



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0032]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food Labeling; Notification Procedures for Statements on Dietary Supplements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0331. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Food Labeling; Notification Procedures for Statements on Dietary Supplements--21 CFR 101.93
(OMB Control Number 0910-0331)--Extension

Section 403(r)(6) of the FD&C Act (21 U.S.C. 343(r)(6)) requires that FDA be notified by manufacturers, packers, and distributors of dietary supplements that they are marketing a dietary supplement product that bears on its label or in its labeling a statement provided for in section 403(r)(6). Section 403(r)(6) of the FD&C Act requires that FDA be notified, with a submission about such statements, no later than 30 days after the first marketing of the dietary supplement. Information that is required in the submission includes: (1) The name and address of the manufacturer, packer, or distributor of the dietary supplement product; (2) the text of the statement that is being made; (3) the name of the dietary ingredient or supplement that is the subject of the statement; (4) the name of the dietary supplement (including the brand name); and (5) a signature of a responsible individual who can certify the accuracy of the information presented, and who must certify that the information contained in the notice is complete and accurate, and that the notifying firm has substantiation that the statement is truthful and not misleading.

The procedural regulation for this program is codified at 21 CFR 101.93. Section 101.93 provides submission procedures and identifies the information that must be included in order to meet the requirements of section 403 of the FD&C Act.

Description of Respondents: Respondents to this collection of information include manufacturers, packers, or distributors of dietary supplements that bear section 403(r)(6) of the FD&C Act statements on their labels or labeling.

In the Federal Register of January 18, 2013 (78 FR 4153), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one letter in response to the notice. One comment in the letter suggested that electronic submission could potentially decrease the reporting burden. FDA agrees and is in the process of developing a method of receiving submissions electronically.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden ¹					
21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
101.93	2,200	1	2,200	0.75	1,650

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

We believe that there will be minimal burden on the industry to generate information to meet the requirements of section 403 of the FD&C Act in submitting information regarding section 403(r)(6) statements on labels or in labeling of dietary supplements. We are requesting only information that is immediately available to the manufacturer, packer, or distributor of the dietary supplement that bears such a statement on its label or in its labeling. We estimate that, each year, approximately 2,200 firms will submit the information required by section 403 of the

FD&C Act. We estimate that a firm will require 0.75 hours to gather the information needed and prepare a submission, for a total of 1,650 hours ($2,200 \times 0.75$). This estimate is based on the average number of notification submissions received by us in the preceding 3 years.

Dated: March 20, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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